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S. 823

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 15, 1999

Mr. HARKIN (for himself and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To establish a program to assure the safety of processed produce intended for human consumption, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Fruit and Vegetable Safety Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. FINDINGS.

Congress finds that—

(1) persons who process produce for human consumption have the responsibility to prevent or minimize food safety hazards related to their products;

(2) consumption of fresh fruits and vegetables can promote health and prevent disease, and should be encouraged;

(3) rising consumer demand for processed produce, the growing market for various kinds of domestic and imported processed produce, and the increasing variety of processing techniques for produce, are causing newly recognized or unpredicted safety hazards; and

(4) uniform sanitation practices, applied to processing of produce, will minimize these hazards.

SEC. 3. DEFINITIONS.

In this Act:

(1) CONTAMINANT.—The term ''contaminant'' includes a bacterium, a chemical contaminant, a natural toxin, a virus, a parasite, a physical hazard, or other substance, that when found on or in produce can cause human illness or injury.

(2) PROCESS.—The term ''process''—

(A) means to carry out the commercial preparation or manufacture of produce, including—

(i) the freezing, dehydration, salting, sprouting, peeling, coring, stemming, trimming, fermentation, mashing, or shredding of produce;

(ii) the cutting of produce after harvesting;

(iii) the final washing of produce that will be presented for sale so as appear to the average consumer to be ready for consumption without further washing or preparation; and

(iv) the mixing or blending of produce with other produce; and

(B) does not include carrying out the harvesting, washing (except as provided in subparagraph (A)(iii)), waxing, packing, or sorting, of a raw agricultural commodity.

(3) PRODUCE.—The term ''produce''—

(A) means any perishable agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b));

(B)(i) includes, except as provided in clause (ii), a mixture of—

(I) a commodity described in subparagraph (A); and

(II) any other food, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); and

(ii) does not include the other food in the mixture described in clause (i)(II); and

(C) does not include an article used for food or drink for animals, or an article used for a component of such an article.

(4) RAW AGRICULTURAL COMMODITY.—The term ''raw agricultural commodity'' means a perish-

able agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b)) that is a raw agricultural commodity, as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

(5) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

TITLE I—FOOD SAFETY ACTIVITIES

SEC. 101. ADMINISTRATION OF NATIONAL PROGRAM.

(a) IN GENERAL.—

(1) NATIONAL PROGRAM.—The Secretary shall administer a national program for the purpose of protecting human health by ensuring that—

(i) the produce processing industry has effective programs in place to assure the safety of produce processed in the United States; and

(ii) producers of raw agricultural commodities have effective programs in place to assure the safety of those commodities produced in the United States.

(2) BASIS FOR PROGRAM.—The program shall take into consideration the distinctive characteristics of produce processing and the production of raw agricultural commodities.

(b) PROGRAM ELEMENTS.—The program shall provide for implementation of the authorities described in—

(1) sections 402A, 402B, 407A, and 407B of the Federal Food, Drug, and Cosmetic Act, as added in subtitles A and B;

(2) section 113; and

(3) title II.

Subtitle A—Processed Produce

SEC. 111. GOOD MANUFACTURING PRACTICES.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 402 (21 U.S.C. 342) the following:

"SEC. 402A. GOOD MANUFACTURING PRACTICES FOR PRODUCE.

"(a) GOOD MANUFACTURING PRACTICE REGULATIONS.—Not later than 1 year after the date of enactment of this section, the Secretary shall by regulation issue standards for good manufacturing practices for the processing of produce.

"(b) APPLICATION.—

"(1) IN GENERAL.—The regulations issued under subsection (a) shall be the same as the provisions of the good manufacturing practice regulations that apply to the processing of food (notwithstanding any exclusions in Federal law relating to

establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities), except as provided in paragraph (2).

''(2) EXCEPTIONS.—In issuing regulations under subsection (a), the Secretary may modify the provisions described in paragraph (1) if the Secretary determines, for good cause shown and stated together with the regulations, that—

''(A) a modification of such provisions would be more effective to prevent the contamination of, or promote the sanitation of, processed produce; or

''(B) the application of a portion of such provisions would not result in the prevention of contamination of, or promotion of sanitation of, processed produce.

''(c) EFFECTIVE DATE.—The regulations described in subsection (a) take effect 2 years after the date of enactment of this section.

''(d) DEFINITIONS.—In this section:

''(1) CONTAMINANT; PROCESS; PRODUCE.—The terms 'contaminant', 'process', and 'produce' have the meanings given the terms in section 3 of the Fruit and Vegetable Safety Act.

''(2) GOOD MANUFACTURING PRACTICE REGULATIONS.—The term 'good manufacturing practice regulations' means the good manufacturing practice regulations for manufacturing, packing, or holding food, issued under sections 402, 701, and 704 and under section 361 of the Public Health Service Act (42 U.S.C. 264).''.

(b) VIOLATION.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) is amended by adding at the end the following:

''(h) It is an article of produce processed in violation of section 402A.''.

SEC. 112. INSPECTIONS OF PROCESSORS.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 704 (21 U.S.C. 374) the following:

''SEC. 704A. INSPECTIONS OF PROCESSORS.

''(a) NATURE OF INSPECTIONS.—

''(1) IN GENERAL.—The Secretary shall provide for unannounced inspections of processing facilities to determine if produce processed in the facilities is in compliance with the requirements of this Act that relate to produce.

''(2) SCHEDULE.—

"(A) IN GENERAL.—The Secretary shall establish a schedule for the unannounced inspections, which shall provide for—

"(i) annual inspections for the facilities, except as provided in clause (ii); and

"(ii) less frequent inspections for facilities classified as low-risk facilities under subparagraph (B).

"(B) LOW-RISK FACILITIES.—The Secretary may classify processing facilities as low-risk facilities. In making the classification, the Secretary shall classify facilities by considering the hazards associated with the type of produce being processed at a facility, the facility's history of compliance and food safety problems, and such other factors as the Secretary may determine to be appropriate.

"(3) EXAMINATION OF CLASSIFICATIONS.—Each such inspection of a facility shall include an examination of whether the facility is appropriately classified under paragraph (2).

"(b) CONDUCT OF INSPECTIONS.—

"(1) SCOPE.—An inspection under subsection (a) of any facility described in subsection (a) shall extend to all things in the facility (including records

required to be maintained under subsection (d)(1)(A)), processes, controls, and premises) that bear on whether processed produce is in compliance with the requirements of this Act that relate to produce. Access to records may include the copying of the records.

''(2) AUTHORITIES.—In conducting such an inspection, an officer or employee duly designated by the Secretary shall have the same authorities and duties as the officer or employee would have under subsection (a)(1), (c), or (d) of section 704 to inspect establishments in which food is processed.

''(3) REPORT.—Immediately after completion of the inspection, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a written report setting forth any conditions or practices observed that indicate that any produce from the facility is in violation of the requirements of this Act that relate to produce.

''(c) PRODUCT DETENTION AND CONDEMNATION.—

''(1) IN GENERAL.—If, during an inspection conducted under this section, an officer or employee making the inspection determines that processed produce is in violation of the requirements of this Act that relate to produce, the officer or employee

may order the produce segregated, impounded, and if objection is not made within 48 hours after the issuance of the impoundment order, condemned. If objection is made within that 48 hours, processed produce that is perishable may be processed to the extent necessary to prevent spoilage, and the Secretary shall expeditiously commence a hearing regarding the determination and any action required for compliance with the requirements of this Act that relate to produce. The decision of the Secretary following the hearing shall be considered to be a final agency action.

''(2) RELEASE.—If the Secretary determines that, through relabeling or other action, the produce can be brought into compliance with the requirements of this Act that relate to produce, the produce may be released following a determination by the Secretary that the relabeling or other action as specified by the Secretary has been performed.

''(3) DESTRUCTION.—Any processed produce condemned under paragraph (1)—

''(A) in a case in which no objection is made under paragraph (1);

''(B) after the hearing and any judicial review; or

"(C) after failure of the owner, operator, or agent to perform relabeling or other action described in paragraph (2);

shall be destroyed under supervision of the Secretary.

"(d) MAINTENANCE OF RECORDS.—

"(1) IN GENERAL.—The owner, operator, or agent in charge of each processing facility shall maintain such records as the Secretary may prescribe. The records shall be maintained for a reasonable period of time as determined by the Secretary. The records shall include information concerning—

"(A)(i) the origin, receipt, delivery, sale, movement, holding, and disposition of produce processed at the facility;

"(ii) the processing of the produce; and

"(iii) other matters reasonably related to whether produce processed at the facility may be in violation of the requirements of this Act that relate to produce; and

"(B)(i) the origin, receipt, delivery, sale, movement, holding, and disposition of ingredients used in the produce processed at the facility, including sufficient information to permit lot identification to facilitate traceback of

produce found to be adulterated under the requirements of this Act that relate to produce, or to be causing human illness or injury;

"(ii) the identity and amount of ingredients used in the produce;

"(iii) the results of laboratory, sanitation, or other quality control tests performed on the produce or in the facility; and

"(iv) consumer complaints concerning the produce or the packaging of the produce.

"(2) AVAILABILITY OF RECORDS.—The owner, operator, or agent shall—

"(A) make available, during an inspection conducted under subsection (a), the records described in paragraph (1)(A); and

"(B) at the request of the Secretary, if the officer or employee finds as a result of the inspection that produce from the facility is associated with foodborne disease or poses an imminent health hazard, make available for inspection the records described in paragraph (1)(B).

"(e) DEFINITIONS.—

"(1) FACILITY.—The term 'facility' includes any factory, warehouse, or establishment, in which produce is processed.

''(2) PROCESS; PRODUCE.—The terms 'process' and 'produce' have the meanings given the terms in section 3 of the Fruit and Vegetable Safety Act.''.

(b) REMEDIES.—

(1) IN GENERAL.—Paragraphs (f) and (n) of section 301, and section 304(g)(1), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 334(g)(1)) are amended by striking ''section 704'' and inserting ''section 704 or 704A''.

(2) PROHIBITED DISCLOSURES.—Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) is amended by striking ''704,'' and inserting ''704, 704A,''.

(c) CONFORMING AMENDMENT.—Section 742(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(a)(2)) is amended by striking ''section 704'' and inserting ''section 704 or 704A''.

SEC. 113. STATE AND FEDERAL COOPERATION.

(a) IN GENERAL.—The Secretary shall work with the States in undertaking activities and programs that contribute to the national program established under section 111 so that State food safety programs involving the safety of processed produce and the national program function in a coordinated and cost-effective manner. With the as-

sistance provided under subsection (b), the Secretary shall encourage States to—

(1) establish, continue, or strengthen State food safety programs, especially with respect to the regulation of retail commercial food establishments; and

(2) establish procedures and requirements for ensuring that processed produce under the jurisdiction of the State food safety programs is not unsafe for human consumption.

(b) ASSISTANCE.—The Secretary may provide to a State, for planning, developing, and implementing such a food safety program—

(1) advisory assistance;

(2) technical assistance, training, and laboratory assistance (including necessary materials and equipment); and

(3) financial and other assistance.

(c) SERVICE AGREEMENTS.—The Secretary may, under an agreement entered into with a Federal, State, or local agency, use, on a reimbursable basis or otherwise, the personnel, services, and facilities of the agency to carry out the responsibilities of the agency under this Act. The agreement shall provide that any compliance records, notices, or reports that are recorded or issued in connection with activities under the agreement, and are in the posses-

sion of the agency that entered into the agreement shall be made available in accordance with section 552 of title 5, United States Code. An agreement entered into with a State agency under this subsection may provide for training of State employees.

Subtitle B—Raw Agricultural Commodities

SEC. 121. GOOD AGRICULTURAL PRACTICES.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act, as amended by section 111(a), is further amended by inserting after section 402A the following:

"SEC. 402B. GOOD AGRICULTURAL PRACTICES FOR RAW AGRICULTURAL COMMODITIES.

"(a) GOOD AGRICULTURAL PRACTICE REGULATIONS.—Not later than 2 years after the date of enactment of this section, the Secretary, in consultation with the Secretary of Agriculture, shall by regulation issue standards for good agricultural practices for the production of raw agricultural commodities, in order to minimize the adulteration and maximize the safety of those commodities.

"(b) IMPLEMENTATION PLAN.—Not later than 3 years after the date of enactment of this section, the Secretary, in consultation with the Secretary of Agriculture,

shall issue and carry out an implementation plan for the implementation of the standards.

''(c) EFFECTIVE DATE.—The regulations described in subsection (a) take effect 3 years after the date of enactment of this section.

''(d) DEFINITION.—The term 'raw agricultural commodity' means a perishable agricultural commodity, as defined in section 1(b) of the Perishable Agricultural Commodities Act, 1930 (7 U.S.C. 499a(b)) that is a raw agricultural commodity, as defined in section 201.''.

(b) VIOLATION.—Section 402(h) of the Federal Food, Drug, and Cosmetic Act, as added by section 111(b), is amended by inserting before the period the following: ''or a raw agricultural commodity produced in violation of section 402B''.

SEC. 122. INSPECTIONS OF FACILITIES.

(a) IN GENERAL.—Chapter VII of the Federal Food, Drug, and Cosmetic Act, as amended by section 112(a), is further amended by inserting after section 704A the following:

''SEC. 704B. INSPECTIONS OF FACILITIES.

''(a) NATURE OF INSPECTIONS.—Officers and employees duly designated by the Secretary shall have the authority to inspect appropriate facilities to determine compliance with the standards described in section 402B.

''(b) REGULATIONS.—Not later than 2 years after the date of enactment of this section, the Secretary, in consultation with the Secretary of Agriculture, shall by regulation issue procedures for conducting the inspections.

''(c) EFFECTIVE DATE.—Subsection (a) and the regulations described in subsection (b) take effect 3 years after the date of enactment of this section.''.

(b) REMEDIES.—

(1) IN GENERAL.—Paragraphs (f) and (n) of section 301, and section 304(g)(1), of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)), as amended in section 112(b), are further amended by striking ''or 704A'' and inserting '', 704A, or 704B''.

(2) PROHIBITED DISCLOSURES.—Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(j)), as amended in section 112(b), is further amended by inserting ''704B,'' after ''704A,''.

(c) CONFORMING AMENDMENT.—Section 742(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379l(a)(2)), as amended in section 112(c), is further amended by striking ''or 704A'' and inserting '', 704A, or 704B''.

TITLE II—RESEARCH AND EDUCATION

SEC. 201. PUBLIC HEALTH ASSESSMENT SYSTEM.

(a) COOPERATION WITH THE CENTERS FOR DISEASE CONTROL AND PREVENTION.—The Commissioner of Food and Drugs, in cooperation with the Secretary of Agriculture, the Director of the Centers for Disease Control and Prevention, and the Administrator of the Environmental Protection Agency, shall establish and maintain an active surveillance system, for surveillance of a representative proportion of the population of the United States, to assess more accurately the frequency and sources of human illness in the United States associated with the consumption of produce.

(b) PUBLIC HEALTH SAMPLING.—

(1) GUIDELINES.—Not later than 12 months after the date of enactment of this Act, the Commissioner of Food and Drugs, in cooperation with the Secretary of Agriculture, the Director of the Centers for Disease Control and Prevention, and the Administrator of the Environmental Protection Agency, shall establish guidelines for a sampling system under which the Commissioner and the Secretary of Agriculture shall collect and analyze samples of produce to assist the Commissioner in carrying out

this Act and the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that relate to produce, and to assess more accurately the nature, frequency of occurrence, and amounts of contaminants in the produce.

(2) MONITORING AND OTHER INFORMATION.—In carrying out the sampling system, the Commissioner of Food and Drugs and the Secretary of Agriculture shall provide for—

(A) statistically valid monitoring, including the conduct of market-basket studies, on the nature, frequency of occurrence, and amounts of contaminants in produce available to consumers; and

(B) at the request of the Commissioner, the collection and analysis of such other information, including analysis of information from monitoring and verification samples, as the Commissioner determines may be useful in assessing the occurrence of contaminants in produce.

(3) PROCESS VERIFICATION STANDARD.—The Commissioner of Food and Drugs and the Secretary of Agriculture shall conduct sampling to identify—

(A) a contaminant, or other substance, that is commonly found on processed produce and, when present at low levels, accurately indicates that the produce has been appropriately processed, with adequate sanitation; and

(B) a standard for the level of that substance that indicates that the produce has been processed as described in subparagraph (A).

SEC. 202. PUBLIC EDUCATION AND ADVISORY SYSTEM.

(a) PUBLIC EDUCATION.—The Commissioner of Food and Drugs, in cooperation with private and public organizations, including the State cooperative extension services and appropriate State entities, shall design and implement a national public education program on food safety relating to produce. In carrying out the program, the Commissioner shall—

(1) provide information to the public regarding Federal standards and good manufacturing practice requirements relating to food safety and promote public awareness, understanding, and acceptance of the standards and requirements; and

(2) provide such other information or advice to the produce processing industry, the food service and retail industry, consumers, and other persons as the

Commissioner determines will promote the purposes of this Act.

(b) HEALTH ADVISORIES.—The Commissioner of Food and Drugs, in cooperation with the Secretary of Agriculture, the Director of the Centers for Disease Control and Prevention, the Administrator of the Environmental Protection Agency, States, and other appropriate entities, shall—

(1) develop and distribute regional and national advisories concerning food safety relating to produce;

(2) develop standardized formats for written and broadcast advisories concerning food safety relating to produce; and

(3) incorporate State and local advisories, at the election of the States and local entities, concerning food safety relating to produce into the national public education program required under subsection (a).

SEC. 203. RESEARCH.

(a) IN GENERAL.—The Commissioner of Food and Drugs shall conduct research to assist in the implementation of this Act and the requirements of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) that relate to produce, including studies relating to—

(1) improving sanitation and food safety practices in the processing of produce;

(2) developing improved techniques for the monitoring of produce and inspection of produce;

(3) developing efficient, rapid, and sensitive methods for determining and detecting the presence of contaminants in produce;

(4) determining the sources of contamination of produce, including contamination from growing, harvesting, and processing produce and post-processing contamination of produce; and

(5) developing consumption data with respect to produce (including processed produce).

(b) CONTRACT AUTHORITY.—The Commissioner of Food and Drugs is authorized to enter into contracts and agreements with States, institutions of higher education, other government agencies, and other persons to carry out the activities described in this section.

TITLE III—IMPORTED FOOD

SEC. 301. CRITERIA FOR DEEMING IMPORTED FOOD ADULTERATED.

(a) AMENDMENT TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342), as amended by

sections 111(b) and 121(b), is further amended by adding at the end the following:

''(i) If it is food consisting of processed produce or a raw agricultural commodity (as defined in section 402A or 402B) that is offered for import into the United States and that has not been prepared, packed, and held under a system or conditions, or subject to measures, that meet the requirements of this Act (including sections 402A and 402B), or that otherwise achieve the level of protection required, as determined by the Secretary, for such food prepared, packed, or held in the United States. In determining whether a system, conditions, or measures meet the requirements of this Act or otherwise achieve the level of protection required, the Secretary may consider whether an officer or employee duly designated by the Secretary has requested, and has been refused, access to the establishment or location where such food was prepared, packed, or held for the purpose of inspection (including sample collection), including inspection under subsection (a)(1), (b), or (d) of section 704A or section 704B, testing, or other relevant procedures, at a reasonable time and in a reasonable manner, and may deny the importation of such food from such establishment or location on the basis of such refusal and other relevant factors.''.

(b) IMPLEMENTATION OF AUTHORITY; PLAN.—The Secretary of Health and Human Services shall develop a plan for the initial implementation of the authority under section 402(i) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), and shall carry out the authority of such section consistent with such plan.

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